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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEFANIE LATTNER, ERIC W. STARR, EUGENE N.
SCARBERRY, and DOUGLAS M. MECHLENBURG

Appeal 2009-002660
Application 10/623,328
Technology Center 3700

Decided: August 13, 2009

Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the Patent Applicants' appeal from the Patent Examiner's rejections of claims 43-58 and 60 as obvious. Jurisdiction for this appeal is under 35 U.S.C. § 6(b). The obviousness rejections are affirmed-in-part.

STATEMENT OF THE CASE

“Obstructive sleep apnea (OSA) is a medical condition in which the upper airway is repeatedly occluded during sleep despite continued respiratory effort. Those afflicted with OSA experience sleep fragmentation and complete or nearly complete cessation of ventilation intermittently during sleep with potentially severe degrees of oxyhemoglobin desaturation.” (Spec. 1:13-17.) “An OSA sufferer typically experiences many apnea and/or hyponea events throughout the night.” (*Id.* at 17-18.) “Symptoms of OSA include snoring, choking and/or gasping during sleep, fragmented sleep, daytime sleepiness, fatigue and poor concentration.” (*Id.* at 20-21.) Therapeutic remedies are available for treating OSA, but none are successful in all cases. (*Id.* at 3:18.)

The Specification describes an “an intraoral electromuscular stimulation device that delivers intraoral electrical stimulation to a patient to reduce or minimize airway closure” to treat breathing disorders, such as OSA. (*Id.* at 6:14-19.)

Claims 43-58 and 60 are pending and appealed. The Examiner rejected the claims as follows:

- Claims 43-47, 49-54, and 56 under 35 U.S.C. § 103(a) as obvious in view of Meer (U.S. Pat. No. 5,190,053, Mar. 2, 1993) and Halstrom (U.S. Pat. No. 5,365,945, Nov. 22, 1994);

- Claims 48 and 55 under 35 U.S.C. § 103(a) as obvious in view of Meer, Halstrom, and Durkan (U.S. Pat. No. 4,414,982, Nov. 15, 1983); and
- Claims 57, 58, and 60 under 35 U.S.C. § 103(a) as obvious over Meer.¹

Claims 43, 50, 57, and 60 are representative and read as follows:

43. A system for treating a breathing disorder comprising:
electromuscular stimulating means for providing electrical energy to a sublingual location of a patient; and
mandibular positing means for controlling a position of such a patient's mandible relative to an upper dentition of such a patient.
50. A method of treating a breathing disorder comprising:
providing electrical energy to a sublingual location of a patient; and
controlling a position of such a patient's mandible relative to an upper dentition of such a patient.
57. An intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient, the device comprising:
a first electrode;
a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity;
a second electrode;
a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode;
a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof; and

¹ The Examiner stated that the claims were rejected in view of Meer and *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (Ans. 5). *Aller* was cited for the legal principle that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” (Ans. 5.) As *Aller* is not prior art to the claims, we have not included it in the statement of the rejection.

a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishes between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and the second electrodes at a stimulation start time between 100-200 ms prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration.

60. An intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient, the device comprising:

- a first electrode;

- a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity posterior to a frenulum and generally proximate to one of a first molar, a second molar, and a third molar of such a patient;

- a second electrode;

- a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity and posterior relative to the first electrode, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode;

- a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof; and

- a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishing between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and second electrodes at a stimulation start time prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration.

OBVIOUSNESS REJECTION OVER MEER AND HALSTROM

Claims 43-47, 49-54, and 56 stand rejected under 35 U.S.C. 103(a) as obvious in view of Meer (U.S. Pat. No. 5,190,053, Mar. 2, 1993) and Halstrom (U.S. Pat. No. 5,365,945, Nov. 22, 1994).

Scope and content of the prior art

The Meer patent

1. According to Meer, tongue and jaw positioners “have been partially effective” for treating obstructive sleep apnea syndrome “but these measures are inconvenient, cumbersome and uncomfortable, which makes their continued use for long periods unlikely.” (Col. 1, ll. 50-55.)
2. Meer also states that “submental electrical stimulation can reverse upper airway obstruction, presumably by contracting the genioglossus muscle, which produces an anterior displacement of the base of the tongue.” (Col. 1, l. 66 to col. 2, l. 2.)
3. However, Meer states that studies
have suggested that submental electrical stimulation is not effective in many patients because electrical current must be passed through skin, subcutaneous tissue and genioglossus muscle. The amount of current required causes pain in many patients. It is possible to more effectively stimulate the genioglossus muscle by using electrodes implanted subcutaneously, but this procedure exposes patients to the risk of infection, pain and complications such as hypoglossal nerve and genioglossus muscle damage. There are also risks associated with general anesthesia.
(Col. 2, ll. 6-17.)

4. Meer describes an intra-oral, sublingual electrode device for the electrical stimulation of a genioglossus tongue muscle using non-invasive electrodes. (Abstract; Col. 2, ll. 25-30.)

5. The device provides a first electrode “in contact with the mucosa of the floor of, and on one side of the frenulum of, a patient’s mouth and a second electrode . . . in contact with the mucosa on the other side of the frenulum.” (Col. 2, ll. 40-44.) The frenulum is the small fold of tissue that extends from the floor of the mouth to the midline of the underside of the tongue (Spec. 13).

6. A pulse generator is connected to the electrodes “having an output providing pulses of selectable mode, polarity, amplitude, current, pulse width and frequency.” (Col. 2, ll. 45-48.)

7. The electrodes are provided with a “support means within a mouth so that the electrodes are effectively and comfortably in contact with the mucosa.” (Col. 2, ll. 49-51.)

8. The electrical pulses “pass from at least one electrode on one side of the frenulum, through the genioglossus muscle, to at least one electrode on the other side of the frenulum.” (Col. 2, ll. 52-55.)

9. One type of support member has “a plurality of electrodes 12 mounted to or within the support member 24 to provide a like number of exposed surfaces to contact associated mucosa. These electrodes may be electrically connected together (not shown) within the body of the support member 24 so that only one conductor need be routed therefrom.” (Col. 5, ll. 61-68; Fig. 9.)

10. Meer also describes a configuration in which the inspiratory efforts of a patient are monitored and, if respiratory distress is observed, an electrical

signal is generated to stimulate muscles that move the patient's tongue anteriorly to maintain upper airway patency. (Col. 2, ll. 56-66.)

11. Meer describes an embodiment of its sublingual electrode device that includes a third electrode which provides submental contact with the skin beneath a patient's chin. (Col. 6, ll. 1-7; Fig. 10.)

The Halstrom patent

12. Halstrom describes an intra-oral dental appliance to be worn by a patient during sleep for treatment of obstructive sleep apnea and snoring.

13.

The dental appliance includes an upper member conforming to the patient's maxillary dentition, a lower member conforming to the patient's mandibular dentition, and connecting means for releasably coupling the upper and lower members together. The connecting means adjustably maintains the lower member in an anterior, protruded position relative to the upper member while permitting a limited degree of lateral movement of the lower member relative to the upper member in the protruded position.

(Col. 2, ll. 45-54.)

Claim 43

Claim 43 is to a system for treating a breathing disorder comprising:

- “electromuscular stimulating means for providing electrical energy to a sublingual location of a patient” and
- “mandibular positing means for controlling a position of such a patient's mandible relative to an upper dentition of such a patient.”

Statement of the Issue

The Examiner found that Meer described an “electromuscular stimulating means” and Halstrom described a “mandibular positing means,” each device which meets the corresponding limitations of the claim. (*See* Ans. 3-4; FF3 & 12.) The Examiner found that the difference between the system of claim 43 and the Meer and Halstrom teachings was that neither Meer nor Halstrom described a system with both the stimulating and mandibular positing means as recited in claim 43. However, the Examiner found that persons of ordinary skill in the art would have been prompted to combine the devices taught by Meer and Halstrom in a system

in order to provide supplemental apnea therapy. Note that Meer discloses that neither mandibular positioners nor geniglossus muscle stimulators are completely effective at treating obstructive sleep apnea (Col 1 ll. 56-59).

(Ans. 4.)

Appellants do not dispute that Meer and Halstrom individually teach the elements of claim 43. However, Appellants contend that the Examiner failed to provide adequate reason to have combined Meer and Halstrom. (Reply Br. 15.) Appellants also contend that Meer “teaches away” from the combination because Meer teaches the disadvantages of the prior art mandibular positioning devices. (*Id.* at 18.) Appellants also challenge the Examiner’s finding that Meer taught the ineffectiveness of intra-oral electromuscular stimulation. (*Id.* at 17.)

Analysis

The issue in this case boils down to whether it would have been obvious to a person of ordinary skill in the art to put two devices together in

a single system for treating a sleep disorder, each of which was known in the prior art to be useful for the same purpose.

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). “[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

In this case, the Examiner found that the ordinary skilled worker would have been prompted to combine the Meer and Halstrom devices “in order to provide supplemental apnea therapy” (Ans. 4). In reaching this conclusion the Examiner found that Meer taught that geniglossus stimulation was not completely effective at treating sleep apnea. (*Id.*) Appellants challenge this finding.

Appellants are correct that the Examiner erroneously cited column 1, lines 56-59, of Meer for teaching that geniglossus stimulation is not completely effective for sleep apnea. However, despite the factual error, the Examiner reached the correct conclusion that the subject matter of claim 43 would have been obvious to a person of ordinary skill in the art.

Appellants have not distinguished the claimed stimulating means from Meer’s nor the claim positing means from Halstrom’s. It is therefore undisputed by Appellants that claim 43 is a combination of two prior art devices. As stated by the U.S. Supreme Court:

For over a half century, the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions ... obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 . . . (1950). This is a principal reason for declining to allow patents for what is obvious.

KSR, 550 U.S. at 415-416. We find this holding equally applicable here where the claimed system is a combination of two prior art devices without any change in their function.

Similarly, in *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), the subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine.

The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60–62 . . . In those circumstances, “while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented,” and the patent failed under § 103. *Id.*, at 62 . . . (footnote omitted).

KSR, 550 U.S. at 417.

In sum, as claim 43 is directed to a device which “unites old elements with no change in their respective functions,” we conclude that the combination would have been obvious to persons of ordinary skill in the art.

Appellants contend that the combination is improper because Meer teaches disadvantages of jaw positioners and therefore persons of ordinary

skill in the art would not have been prompted to combine it with Meer's stimulator.

A "finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable, combination." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). In other words, an invention may be suggested by the prior art and therefore obvious, even if inferior, less desirable, or simply alternative to embodiments that would be made by following other prior art suggestions. Thus, even though a jaw positioner would have been known to have certain disadvantages when used to treat sleep apnea, persons of skill in the art would have still been prompted to combine it with Meer to supplement Meer's intra-oral sublingual stimulation.

Appellants also argue that the Examiner improperly combined Meer with Halstrom because the "stated object of Meer is to treat breathing disorders using a sublingual stimulation device which overcomes the disadvantages of prior art devices" (Reply Br. 18). As we understand it, Appellants' position is that since Meer does not teach that its sublingual stimulation device is ineffective, there would have been no reason to have combined it for "supplemental apnea therapy" as reasoned by the Examiner.

The evidence does not support Appellants' argument. Notwithstanding Meer's statement that "none [of the prior art] disclose the advantages" of its sublingual stimulation device (Col. 2, ll. 18-22), Meer still combines it with another device characterized in its background section as "not effective in many patients" (FF3). At Column 6, lines 1-17, Meer describes an embodiment of its sublingual electrode device that includes a

third electrode which provides submental contact with the skin beneath a patient's chin. (FF11.) The device is shown in Meer's Figure 10. Submental stimulation was expressly stated by Meer to be ineffective in many patients and to cause pain. (FF3.) Yet, Meer was still motivated to combine its "effective, convenient and comfortable" sublingual stimulation device with submental stimulation, a modality admitted to have faults. Accordingly, the Examiner properly inferred from Meer that the skilled worker would have been prompted to combine sublingual stimulation device with the jaw positioner, despite its acknowledged shortcomings.

Claim 44

Claim 44 is to the system of claim 43

wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode in sublingual positions within a patient's oral cavity such the second electrode is located in a position posterior to the first electrode to deliver the electrical energy in an anterior-to-posterior direction or a posterior to-anterior direction.

Appellants contend this limitation is not satisfied by Meer because "Meer fails to teach or suggest locating the second electrode posterior to the first electrode." (Reply Br. 19.)

This argument is not persuasive. Claim 44 is to a system, not a treatment method. Therefore, it does not require the electrodes to be positioned in a patient's oral cavity, only that they be capable of assuming the claimed position, if so desired. As Meer describes support means for positioning the electrodes (FF7), it is reasonable to believe that they could be positioned within the oral cavity with one posterior to the other as recited in

the claim. Likewise, as Meer's device has a pulse generator connected to the electrodes, it would have been reasonable to believe that it could have been used to deliver electrical energy in the direction specified in the claim.

Claims 45 and 52

Claim 45 is to the system of claim 43 "wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode on a same side of a patient's oral cavity." Claim 52 is to a method of using a positioning means having the same features as in claim 45.

The Examiner found that Meer taught an embodiment with a plurality of electrodes within a single support member that would be placed on the same side of a patient's oral cavity (FF9; Ans. 8). Appellants do not identify a defect in the Examiner's finding, and as we find none, we affirm the rejection of claim 45 and 52.

Claim 46

Claim 46 is to the system of claim 43 "wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode posterior to the frenulum." Once again, as discussed above for claim 44, we interpret this limitation to be an intended use of the claimed positioning means. Therefore, the issue is whether the positioning means of Meer would have reasonably been believed to be capable of being positioned as in the claim, not whether it was actually used in this manner. As Appellants have not pointed to any structural deficiency in Meer's

“support means” (FF7), we conclude that the claim limitation is satisfied by Meer.

Claim 50

Claim 50 is to a “method of treating a breathing disorder” comprising:

- “providing electrical energy to a sublingual location of a patient”; and
- “controlling a position of such a patient's mandible relative to an upper dentition of such a patient.”

Appellants contend that the claim 50 is patentable “for the same reasons” discussed for claim 43. As there is no evidence that the device of claim 43 would function any differently when used to treat a breathing disorder as the Meer and Halstrom devices would perform when used alone, we affirm the rejection for the same reasoning as for claim 43.

Claim 51

Claim 51 is to the method of claim 50,
positioning a first electrode and a second electrode in sublingual positions within such a patient's oral cavity such that the second electrode is located in a position posterior relative to the first electrode; and applying an electrical stimulation via the first electrode and the second electrode so as to deliver electrical energy to a patient in an anterior-to-posterior direction or a posterior-to anterior direction.

The issue is whether Meer describes or suggests placing its electrodes in the oral cavity and applying electrical energy as recited in the claim.

The limitations of claim 51 are not met by Meer. Appellants state in the Specification that locating at least one electrode posterior to another “is done because the present inventors also discovered that optimum stimulation results are achieved if the stimulation current flow through the patient is in a generally anterior-to-posterior or posterior-to-anterior direction.” (Spec. 15:8-11.)

The Examiner contends that “current flowing between Meer electrodes 12 on the same support structure 24 or different support structure passes through the volume conductor of the geniglossus muscle and as such will have at least a small component in the posterior to anterior direction regardless of how posterior and anterior are defined” (Ans. 7).

We agree that Meer discloses pulsing electrical current from an electrode on one side of the frenulum to at least one electrode on the other side (FF 8). We also agree that Meer discloses an embodiment with at least one electrode positioned posterior to another electrode (*see* FF9; Figure 9). However, the Examiner has not explained how or why passing a current through the genioglossus muscle as described in Meer would necessarily result in a posterior to anterior current flow, or anterior to posterior current flow, as required by claim 51. We therefore reverse the rejection of claim 51.

Claim 53

Claim 53 is to method claim 50 “wherein providing electrical energy includes locating a first electrode and a second electrode posterior to the frenulum.” The issue is whether Meer describes or suggests placing its electrodes in the oral cavity as recited in the claim.

Meer describes positioning the electrodes on either side of the frenulum (FF5), not posterior to it. Accordingly, we reverse this rejection. See discussion above for claim 51.

OBVIOUSNESS REJECTION OVER MEER, HALSTROM AND DURKAN

Claims 48 and 55 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Meer, Halstrom, and Durkan.

The Durkan patent

- 14. Durkan describes a respirator apparatus comprising an apneic event circuit and a demand gas circuit. (Abstract.)
- 15. The apneic event circuit detects when an apneic event occurs and activates a signal. (Abstract.)
- 16. The demand gas circuit supplies respiratory gas to a patient at the beginning of an inspiration for a time period. (Abstract.)

Specification

- 17. According to the Specification, it is “known to apply positive air pressure at the mouth and/or nose of the patient” to treat obstructive sleep apnea. (Spec. 3:4-6.)

Statement of the Issue

Have Appellants shown that the Examiner erred in concluding that it would have been obvious to have provided positive air pressure in a system and method for treating apnea?

Analysis

Claims 48 and 55 depend on claims 43 and 50, respectively, and further comprise a means for applying positive pressure to an airway of the patient. The Examiner found that it was “well known that positive air pressure devices are used to treat sleep apnea and a PHOSITA would have found it obvious to supplement the therapy of Meer with the therapy of Durkan in order to provide increased treatment.” (Ans. 9.)

Appellants contend that the Examiner has not provided an “explicit rationale explaining why” the ordinary skilled artisan would have combined Durkan with the Meer and Halstrom teachings. (Reply Br. 24.) Appellants contend that Durkan fails to teach that the short burst of oxygen can be used to treat a sleep apnea, but rather teaches the breathing cycle is monitored and, if an apneic event is detected, an alarm is sounded. (*Id.*)

Appellants’ argument is not persuasive. First, the Examiner did provide an explicit rationale for combining the prior art: to “provide increased treatment” for sleep apnea. (Ans. 9.) Secondly, Appellants admit that it was known to treat sleep apnea with positive air pressure. (FF17.) Thus, the Examiner’s statement that it was well known to treat sleep apnea with positive air pressure is supported by Appellants’ own admission. Accordingly, while Durkan does not expressly teach that its demand gas circuit can be used for an apneic patient, persons of ordinary skill would have recognized it would be useful for this purpose – especially in view of the fact that Durkan is also concerned with sleep apnea.

For the foregoing reasons, we affirm the rejections of claim 48 and 55.

OBVIOUSNESS REJECTION OVER MEER

Claims 57, 58, and 60 stand rejected under 35 U.S.C. § 103(a) as obvious over Meer.

Claim 57 and 60

Claims 57 and 60 are directed to an intraoral electromuscular stimulation device comprising first and second electrodes, a sensor adapted to detect a respiratory parameter of the patient, and a control unit coupled to the sensor. The claims require the second electrode to be positioned posterior to the first electrode and the control unit to stimulate in anterior-to-posterior or posterior-to-anterior direction for a specific period of time and/or frequency. Claim 58 depends on claim 57 and therefore incorporates all its limitations.

The Examiner has not provided an adequate evidence-based explanation as to why Meer's device would be capable of performing the claimed anterior-to-posterior/posterior-to-anterior stimulation, or why a person of ordinary skill in the art would have configured Meer's device to deliver electrical energy in the direction and frequency as specified in the claim.

Conclusion of Law

The Examiner did not err in concluding that it would have been obvious to a person of ordinary skill in the art to have put Meer's intra-oral, sublingual electrode device and Halstrom's intra-oral dental appliance together in the same system for treating a sleep disorder as recited in claims 43 and 50.

The Examiner did not err in concluding that it would have been obvious to have provided positive air pressure in a system and method for treating apnea as in claims 48 and 55.

The Examiner erred in determining it was obvious to have placed Meer's electrodes in the oral cavity in the orientation recited in claims 51 and 53.

Summary

The obviousness rejections of claims 43, 44, 45, 46, 48, 50, 52, and 55 are affirmed. Claims 47, 49, 54, and 56, fall with these claims because separate arguments for the patentability of claims were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

The obviousness rejections of claims 51, 53, 57, 58, and 60 are reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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